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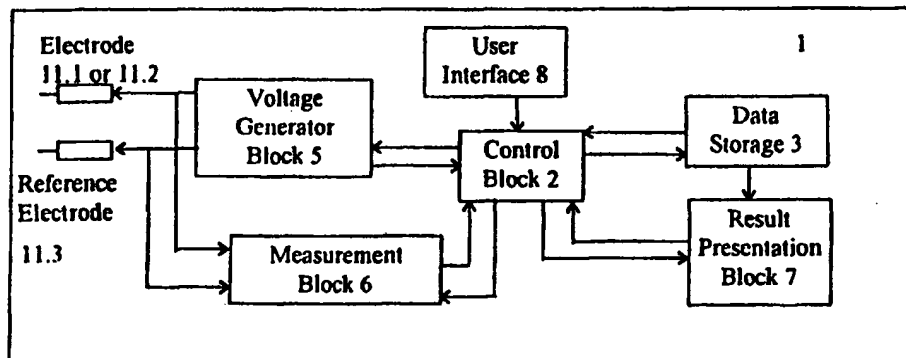
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(54) Title: APPARATUS FOR EVALUATION OF SKIN IMPEDANCE VARIATIONS



(57) Abstract

The invention provides an apparatus and method for automatic evaluation of skin resistance or impedance variations in order to diagnose the state of health of at least a portion of a human or animal body. The difference between an AC impedance measured at a specific frequency and at a specific skin area with a calibration electrode and a reference electrode and the impedance measured at a similar frequency and in the same area with a measurement electrode and a reference electrode, is used to determine the state of health of the internal organ corresponding to the examined skin area. Alternatively, the skin between the electrodes is exposed to a DC potential of a magnitude selected to give a break-through effect. The resistance of the skin is measured between a measurement electrode polarised negatively with respect to a reference electrode, and the DC resistance of the same skin area is again measured but with the measurement electrode polarised positively with respect to the reference electrode. The ratio of these two values is used to determine the state of health of the internal organ corresponding with the examined skin area.

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APPARATUS FOR EVALUATION OF SKIN IMPEDANCE VARIATIONS

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Background to the Invention

This invention relates to an apparatus and method for automatic evaluation of
15 skin impedance variations in order to estimate the state of health of the internal organs of a human or animal.

Existing methods of utilising skin impedance values for organ diagnostics base their results on non-ratiometric measurements of basic skin impedance and produce
20 inconsistent and unreliable results which depend on numerous variables, including the emotional state of the patient, muscular tension, measurement time, the contact area and pressure of the measuring electrode and various physiological differences between individuals.

After many years of research the inventor now believes that the internal organs of the body of a human or animal have corresponding areas on the skin where information regarding the corresponding internal organs can be retrieved by measuring the electrical properties of said skin. The inventor further believes that said
5 corresponding areas of the skin have other properties related to the science of reflexive pyhsiotherapy (including acupuncture), for example, the ability to heal and /or relieve pain caused by the corresponding organs.

The inventor believes yet further that these corresponding areas of the skin may
10 be mapped, which map is applicable to various individuals.

The inventor has found that the ear auricle may be particularly accurately mapped and is most suitable for the method of the invention since in most cultures the skin of the ear is exposed and may be examined without any garments having to be
15 removed.

In this specification, unless the context clearly indicates to the contrary, the term "impedance", is to be understood to include resistance.

20 **Summary of Invention**

The impedance variation can be measured in two ways:

Method 1: AC evaluation.

The difference between the AC impedance measured at a specific frequency
5 and at a specific skin area with a calibration electrode and a reference electrode and the
impedance measured at a similar frequency and in the same area with a measurement
electrode and a reference electrode, is used to determine the state of health of the
internal organ corresponding to the examined skin area. The calibration electrode and
reference electrode contact areas are relatively larger than the measurement electrode
10 skin contact area.

Method 2: DC evaluation

The term "break-through effect" refers to the sudden and significant drop in
15 skin electrical resistance witnessed after a sufficient potential difference is applied
between the electrodes.

The skin between the electrodes is exposed to a DC potential of a magnitude
selected to give the break-through effect. The DC resistance of the skin is measured
20 between a measurement electrode polarised negatively with respect to a reference
electrode, and the DC resistance of the same skin area is again measured but with the
measurement electrode polarised positively with respect to the reference electrode.
The ratio of these two values is used to determine the state of health of the internal
organ corresponding with the examined skin area.

An apparatus broadly in accordance with the invention may include the following functional blocks:

- 5 A measurement and/or calibration electrode, a reference electrode, a voltage generator block, a measurement block, a control block, a user interface block, a result presentation block and, optionally, a data storage block.

10 The voltage generator block generates a potential difference between the measurement electrode and the reference electrode, or the calibration electrode and the reference electrode. The voltage generator block is connected to and controlled by the control block. The measurement block is connected to the measurement electrode and the reference electrode (Fig 1).

- 15 The measurement block determines the impedance between the measurement electrode and the reference or calibration electrode. Alternatively the voltage generator block can be connected through the measurement block to the measurement electrode or the reference electrode (Fig 2). The ultimate purpose of the measurement block is to measure a parameter (such as voltage or current) that can be used to
20 determine the impedance or resistance between the measurement electrode and the reference electrode. The measurement block is connected to the control block.

 The control block is connected to the user interface block (if present), the data storage block (if present), the result presentation block, the voltage generator block

and the measurement block. The control block sets the voltage generated by the voltage generator block. The control block uses information received from the measurement block to detect the break-through effect, and the resistance asymmetry. The control block can store and retrieve information in the data storage block (if present). The control block informs the user of the results of the measurements through the result presentation block. The result presentation block may generate a visual or audio indication to inform the user of the result i.e. the state of health of the internal organ, obtained by the control block.

10 Description of Operation

After a great deal of experimental work the inventor has found that an apparatus broadly in accordance with the invention may be operated as described below to obtain reliable results.

15

Technique 1: AC evaluation

The calibration electrode is placed in contact with the relevant skin area corresponding to the internal organ of a subject the state of health of which is to be determined. The reference electrode is placed in contact with any other skin area, usually the hand of the subject. The control block uses the voltage generator block to generate an AC signal of specific frequency and magnitude between the calibration and reference electrodes. The control block determines the impedance between the electrodes via the measurement block. The control block stores the impedance value

in the data storage block (referred to as "calibration impedance"). The control block signals that the calibration impedance has been determined via the result presentation block. The calibration electrode is removed and the measurement electrode is placed on the skin area undergoing investigation. The control block uses the voltage generator block to generate an AC signal of similar frequency and magnitude between the calibration and reference electrodes.

The control block determines the ratio between the calibration impedance and the impedance measured with the measuring electrode and converts this ratio to an indication of the state of health of the internal organ. The control block displays the result on the result presentation block (e.g. on a disease intensity percentage scale).

Conveniently the result is displayed in percentage format, calculated according to the following equation:

15

$$\% \text{ Disease} = (1 - I_{\text{measurement}} / I_{\text{reference}}) \times 100; \text{ or}$$

$$\% \text{ Disease} = (1 - R_{\text{reference}} / R_{\text{measurement}}) \times 100.$$

Various percentage ranges corresponding to different states of health of the organ. Typically 0 to 40% indicates a healthy state, 40 to 60% indicates the upper limits of the healthy state, 60 to 80% indicates a sub-acute state, and 80 to 100% indicates an acute condition of the internal organ in question.

Technique 2: DC evaluation

The reference electrode is placed in contact with any skin area. The measurement electrode is placed in contact with a specific skin spot corresponding with an internal organ the state of health of which is to be determined. The control block uses the voltage generator block to generate a DC potential difference between the electrodes. The control block determines the resistance between the electrodes via the measurement block. The control block adjusts the DC potential difference and checks the resistance until the resistance falls below a certain threshold or suddenly starts decreasing rapidly (break-through effect). The control block checks the resistance until a stable value is reached. The control block stores this resistance value in the data storage block (referred to as "reference resistance").

The control block inverts the polarisation of the measurement and reference electrodes with respect to each other and uses the voltage generator block to apply a DC potential across the electrodes. The control block determines the resistance between the electrodes via the measurement block (referred to as "measurement resistance").

The control block determines the ratio between the "measurement resistance" and the "reference resistance" and calculates the intensity of disease from this ratio. The following equation is used for the calculation:

$$\% \text{ Disease} = (1 - I_{\text{measurement}} / I_{\text{reference}}) \times 100; \text{ or}$$

$$\% \text{ Disease} = (1 - R_{\text{reference}} / R_{\text{measurement}}) \times 100$$

The control block displays the result on the result presentation block (e.g. on a disease intensity percentage scale).

5

Conveniently the result is displayed in percentage format, with various percentage ranges corresponding to different state of health of the organ. Typically 0 to 40% indicates a healthy state, 40 to 60% indicates the upper limits of the healthy state, 60 to 80% indicates a sub-acute state, and 80 to 100% indicates an acute condition of the internal organ in question.

For best break-through effect induction the reference resistance measurement should be made with the measurement electrode polarised negatively with respect to the reference electrode, although with higher potential differences between the electrodes it is believed that the break-through effect may also be observed if the polarity is inverted.

When using the DC technique, if the internal organ is not healthy a higher resistance will be measured with the measurement electrode polarised positively with respect to the reference electrode than with the measurement electrode polarised negatively with respect to the reference electrode e.g. 300 k Ω as opposed to 30 k Ω . Similarly, when using the AC technique, the measurement obtained using the measurement electrode will have an impedance reading which is higher than that of the measurement obtained using the calibration electrode.

It is also possible to use an AC signal when using the DC technique.

Although both the AC and DC evaluation techniques are effective, for thin skin
5 regions of the body, such as the ear auricle, the DC evaluation technique is preferred,
while for thicker skin areas of the body, such as the feet, the AC method is preferred as
thicker skin areas require higher voltages for the breakthrough effect to occur, which
could be painful for the subject.

10 The inventor believes that an apparatus such as that described above, uses new
measurement technologies and ratiometric techniques and achieves consistent and
repeatable diagnostic results which are independent of various physiological differences
between individuals, the emotional state of a patient, muscular tension and the
measurement time. The results depend on the intensity of the disease, the effect of
15 pressure is insignificant.

Examples

Example 1:

20 In a first test in which a gastric ulcer was diagnosed, the following results were
obtained:

Auricular projection areas (thin skin - DC measurement):

reference resistance = 10 k Ω ;

25 \Rightarrow Stomach projection area: measurement resistance = 200k Ω ;

i.e. 95% of disease activity

⇒ Healthy organ projection areas: measurement resistance = 10 -

25kΩ

i.e. 0-60% of disease activity

5

Pedal projection areas (thick skin - AC measurement):

Reference resistance = 15 kΩ (at 250 Hz)

10 ⇒ Stomach projection area: measurement resistance = 300 kΩ

i.e. 95% of disease activity

⇒ Healthy organ projection areas: measurement resistance =

15 - 37.5 kΩ

i.e. 0-60% of disease activity

15

Example 2:

Pyelonephritis (kidney infection)

Auricular projection areas (thin skin - DC measurement):

20 Reference resistance = 10 kΩ

⇒ Kidney projection area: measurement resistance = 100 kΩ

i.e. 90% of disease activity

⇒ Healthy organ projection areas: measurement resistance = 10 -

25 kΩ

i.e. 0-60% of disease activity

Pedal projection areas (thick skin - AC measurement):

Reference resistance = 10 k Ω (at 250 Hz)

5 \Rightarrow Kidney projection area: measurement resistance = 100 k Ω

i.e. 90% of disease activity

\Rightarrow Healthy organ projection areas: measurement resistance = 10 -

25 k Ω

i.e. 0-60% of disease activity

10

Description of the Drawings

Figure 1 shows, in schematic block diagram representation, an apparatus for evaluation of skin impedance variations and state of health of a corresponding internal organ, using the DC or AC technique of measurement, broadly in accordance with the invention;

Figure 2 shows, in schematic block diagram representation, an alternative implementation of an apparatus for evaluation of skin impedance variations and state of health of a corresponding internal organ, using the DC or AC technique of measurement, broadly in accordance with the invention;

Figure 3 shows, in schematic block diagram representation, an apparatus for evaluation of skin impedance variations and state of health of a corresponding internal organ, using the DC or AC technique of measurement, in accordance with the invention;

Figure 4 shows, in schematic circuit diagram representation, a power supply unit according to Figure 3;

Figure 5 shows, in schematic circuit diagram representation, a control block and a user interface block according to Figure 3;

5 Figure 6 shows, in schematic circuit diagram representation, a result presentation block according to Figure 3;

Figure 7 shows, in schematic circuit diagram representation, a voltage generator block and a measurement block according to Figure 3;

Figure 8 shows, in schematic circuit diagram representation, a data storage
10 block according to Figure 3;

Figure 9 shows a simplified flow diagram of the software used in the microcontroller in the control block in Figure 5;

Figure 10 shows, in graphic representation, the breakthrough effect obtained using the apparatus of the invention in DC measurement mode;

15 Figure 11 shows, in graphic representation, the dependence of skin resistance on applied voltage for a skin spot corresponding to a healthy organ (Figure 11a) and a skin spot corresponding to a diseased organ (Figure 11b), obtained when applying the technique of the invention using the DC measurement technique;

Figure 12 shows, in graphic representation, the dependence of skin impedance
20 on applied frequency, when applying the technique of the invention using the AC measurement technique;

Figure 13 shows, in graphic representation, skin spots on a human ear auricle corresponding to internal organs; and

Figure 14 shows, in graphic representation, skin zones on the sole of a human

foot corresponding to particular internal organs.

In the figures reference numeral 1 broadly indicates an apparatus for determining the state of health of an internal organ of a subject by the impedance variation evaluation method, broadly in accordance with the invention

The apparatus 1 includes a voltage generator block 5 which generates a potential difference between a measurement 11.1 or calibration 11.2 electrode and a reference electrode 11.3. The voltage generator block 5 is connected to and controlled by the control block 2. The measurement block 6 is connected to the measurement electrode 11.1 or calibration electrode 11.2 and the reference electrode 11.3.

In figure 2 reference numeral 1.2 broadly indicates an alternative apparatus for determining the state of health of an internal organ of a subject by the impedance variation evaluation method, broadly in accordance with the invention.

The voltage generator block 5 generates a potential difference between the measurement 11.1 or calibration electrode 11.2 and the reference electrode 11.3. The voltage generator block 5 is connected to and controlled by the control block 2. The measurement block 6 is connected to the measurement electrode 11.1 or calibration electrode 11.2 and the reference electrode 11.3.

The measurement block 6 determines the impedance between the measurement electrode 11.1 or calibration electrode 11.2 and the reference electrode 11.3.

Alternatively the voltage generator block 5 can be connected through the measurement block 6 to the measurement electrode 11.1 or the calibration electrode 11.2 or the reference electrode 11.3. The ultimate purpose of the measurement block 6 is to measure a parameter (such as voltage or current) that is dependent on the impedance or resistance between the measurement electrode 11.1 or calibration electrode 11.2 and the reference electrode 11.3. The measurement block 6 is connected to the control block 2.

The control block 2 is connected to the user interface block 8, the data storage block 3, the result presentation block 7, the voltage generator block 5 and the measurement block 6. The control block 2 sets the voltage generated by the voltage generator block 5. The control block 2 uses information received from the measurement block 6 to detect the breakthrough effect and the resistance asymmetry. The control block 2 can store and retrieve information in the data storage block 3. The control block 2 informs the user of the results of the measurements through the result presentation block 7. The result presentation block 7 may generate a visual or audio indication to the user of the result i.e. the state of health of the internal organ, obtained by the control block 2.

Referring to Figure 3, an electrodermal diagnostic unit 1 is provided which is primarily intended for use in diagnosing internal organ pathology in humans through electric stimulation and impedance measurement of remotely located skin spots.

In the electrodermal diagnostic unit 1 the control block 2 displays instructions

to the operator through LCD display 37 exclusively or in combination with a video monitor connected to the video display unit 13 or a television set connected to the UHF modulator unit 10. Lists of organs that can be diagnosed are displayed on the monitor or television set. The operator selects internal organs to diagnose via the keypad 9.

The control unit 2 selects a method of diagnosis based on the location of the skin spot/zone to be investigated. Two methods of diagnosis are available specifically alternating current measurement (AC measurement) or direct current measurement (DC measurement). AC measurement is better suited to areas with thicker skin such as the soles of the feet. DC measurement is better suited to areas with thin skin such as the ear.

The control unit 2 displays a picture of the region to be investigated (such as the foot or ear). A flashing zone or spot indicates where the measuring electrode 11.1 must be placed by the operator. The control unit 2 controls the voltage generator block 5 through an optical link to execute the selected test.

For DC measurement: The voltage generator block 5 generates a small constant potential difference between the measurement electrode 11.1 and the reference electrode 11.3, with the measurement electrode polarized negatively with respect to the reference electrode. The current is continuously monitored by the control block 2 using the measurement block 6 and when the current rises above a preset threshold, it is assumed that both probes are in contact with the skin. The

potential difference between the probes is slowly increased and the current through the probe measured continuously. The skin resistance is calculated by dividing the value of the potential applied to the probes by the value of the measured current running through the probes. When a sudden significant drop in this resistance is detected (see figure 9 for algorithm) the potential difference between the probes is continuously adjusted so as to maintain the measured current through the probes at a predetermined level. This continues until the rate of change in skin resistance falls below a predetermined level. The value of the potential difference at this time is stored by the control block 2 in the data storage block 3. The control block 2 uses the voltage generator block to apply the same potential difference between the probes with opposite polarization (the measurement electrode positively polarized with respect to the reference electrode). The current is continuously measured. The ratio (measured current)/(preset current) is believed to give an indication of the degree of pathology in a particular organ. If this ratio is close to zero, the relevant organ is believed to be diseased. If this ratio is greater than 0.6 then the relevant organ is believed to be healthy. The closer this ratio is to zero, the greater the degree of pathology (e.g. cancer) is believed to be present in the organ.

The control block 2 monitors the current via the measurement block 6 and displays the test result on the LCD display 37 on a disease percentage scale until the operator presses the foot pedal 12. The control block stores the test result in the data storage block 3, and activates the buzzer 36 to indicate the completion of the test.

For AC measurement: The operator places the reference electrode 11.3 and the

calibration electrode 11.2 on the skin of the subject when prompted via the LCD display 37. The voltage generator block 5 generates a small constant potential difference between the electrodes 11.2,11.3. The current is continuously monitored and when the current rises above a preset threshold, it is assumed that both probes are in contact with the skin. An sinusoidal alternating voltage is now applied between the electrodes. The current is monitored continuously by the control block 2 using the measurement block 6 and the voltage adjusted until the current reaches a preset level. This process is referred to as calibration.

10 The control unit 2 displays a picture of the region to be investigated (typically the foot) on the video monitor or television screen using the result presentation block . The control unit 2 displays a message on the LCD display 37 informing the operator that the measuring electrode 11.1 and the reference electrode 11.3 must now be used. A flashing zone or spot indicates where the measuring electrode 11.1 must be placed by the operator. The current is continuously measured. The ratio (measured current)/(preset current) is believed to give an indication of the degree of pathology in a particular organ. If this ratio is close to zero, the relevant organ is believed to be diseased. If this ratio is greater than 0.6 then the relevant organ is believed to be healthy. The closer this ratio is to zero, the greater the degree of pathology (e.g. cancer) is believed to be present in the organ. The control block 2 monitors the current via the measurement block 6 and displays the test result on the LCD display 37 on a disease percentage scale until the operator presses the foot pedal 12. The control block stores the test result in the data storage block 3, and activates the buzzer 36 to indicate the completion of the test.

The control unit 2 consists of a microcontroller 16 (typically an 8051). An oscillator 28 provides a clock signal for the microcontroller 16. A standard address latch (11) configuration is used to create a 16 bit address bus (11.1,16.3) which connects to 32K random access memory 56 and 32K read only memory 57. A bidirectional data bus 16.1 transports data to and from the microcontroller 16. The microcontroller 16 interfaces with a keypad 9 using keypad interface 17, (typically 74HC922)

The electrodes are galvanically isolated 55 from the main circuit by a transformer 43 in the voltage generator block 5. The measurement block 6 is optically isolated from the main circuit by optocouplers 51,52,53,54. A sinusoidal voltage applied to the primary coil of transformer 43.1 is stepped up by the secondary coil 43.2. Voltage doubling circuit 44 doubles and rectifies the sinusoidal output of coil 43.2 so that a constant voltage appears over capacitor 38. When relay 40 is off an alternating voltage is fed through to the relay 42. When relay 40 is on, the constant voltage over capacitor 38 is fed through to the relay 42. Relay 42 is used to switch the polarity of the signal from relay 40. This combination of relay 42 and 40 is used to set the voltage between the probes to an alternating voltage or a constant voltage and allows the polarity of the probes to be reversed.

20

The primary coil 43.1 of then transformer 43 is driven by an opamp 41 which is used in inverter amplifier mode. A programmable sinewave generator 39 (typically ML2036) provides the input signal to the opamp 41. Sinewave generator 39 is controlled by the microcontroller 16 via lines 22.1, 22.3, 22.4. The frequency is

digitally programmed via this serial bus. The magnitude of the output sinusoidal signal (half peak to peak) is equal to the voltage on the output 24.1 of a digital to analogue converter 24. The output voltage of the digital to analogue converter 24 is set via bus 16.1 by the microcontroller 16.

5

The current is measured using the measurement block 6. When the circuit between the electrodes is closed by an impedance such as the human body, current is conducted through the electrodes to ground via measuring resistor 46. The voltage appearing over this resistor with respect to ground is therefore proportional to the
10 current through the probes. An opamp buffer 45 feeds the signal to the precision rectifier formed by the opamps referred to by numerals 47 and 48. These extract the absolute value of the signal which is fed into a serial analogue to digital converter (ADC) 49. The ADC 49 communicates with the microcontroller 16 via a serial bus consisting of lines 22.1, 22.2 and 22.3 through an optical link provided by three
15 optocouplers 52,53,54. A zero crossing detector 50 detects the polarity of the voltage over the measuring resistor 46 and transmits this information as a binary one or zero to the microcontroller 16 through an optocoupler 51. When an alternating voltage is applied to the electrodes, current is measured at every voltage peak. The microcontroller 16 waits for a zero to one transition to occur on the output 22.5 of
20 optocoupler 51. The microcontroller 16 waits for a time period equal to one quarter of the period of the output voltage frequency before requesting a conversion from the analogue to digital converter 49.

The microcontroller displays relevant information on a monitor through the

video display unit 13. A dual port ram 30 contains a bit mapped version of the screen.

The microcontroller 16 can read and write data to the dual port ram 30 through a data

bus 16.1 using control lines 16.6 and 16.7 and the address bus, referred to by numerals

11.1 and 16.3. A field programmable gate array (FPGA) 25 uses counters and shift

5 registers to sequentially read bytes of screen data and to write red green and blue

(RGB) pixel information as well as vertical and horizontal retrace information to an

RGB to PAL encoder 31. A universal sync generator 33 generates PAL video standard

synchronization pulses. These pulses are locked to the main system clock using a phase

locked loop 34. The pixel clock is derived from the main system clock 16.5 using

10 counters in the FPGA 25. The pixel clock is used to read and serialize data at the

correct rate and in the correct manner from the dual port ram 30 so that the bit streams

fed to the RGB to PAL encoder can be encoded into a PAL standard composite sync

video signal that can be fed directly into the video input 31.1 of a standard video monitor.

15

The UHF modulator unit 10 converts the composite sync video signal to an ultra high frequency signal that can be directly fed into the aerial port 35.1 of a television set. An integrated UHF modulator 35 modulates the composite sync PAL signal from the video display unit to a frequency determined by external components.

20

Power is delivered to the circuit by the power supply block 4. A transformer 14.1 with primary coupling connected to mains and secondary coupling connected to rectifier bridge 14.2 converts the mains 220VAC to 7.2 VAC. The output of the rectifier is fed into 5V regulator 14.3. A monolithic voltage inverter 15.1 typically a

MAX660 generates a -5V supply from the main 5V supply.

The power supplied to the voltage generator block 5 and the measurement block 6 is galvanically isolated from the main power supply. DC to DC converter 15.2 (typically NMA0505) is used to supply +5V and -5V to the isolated patient interface circuitry.

Figure 10 shows a graph of voltage over a period of time when the breakthrough effect (x) is achieved. At the point of breakthrough (x) a sudden and significant decrease in resistance occurs, and thus a sudden and significant decrease in voltage is also observed. The reference value is measured once the voltage stabilises after the breakthrough effect.

Figures 11a and 11b show how resistance is affected when an organ is diseased. In Figure 11a, the two curves represent resistance values at different voltages for a healthy organ, while figure 11b shows two curves of resistance values at different voltages for an unhealthy organ. Lines 50 represent the reference resistance values, and lines 52 represent the measurement resistance values. Figure 11b shows two curves of resistance values at different voltages for an unhealthy organ. When an organ is healthy, the reference and measurement resistance values are similar, but as the state of disease of the organ increases, so the measurement value increases and the greater the difference between the reference and measurement values.

Similarly, Figure 12 shows how the measurement impedance changes when an

organ is diseased. Line 56 shows reference or resistance values at different frequencies. Line 58 shows measurement resistance values for a healthy organ, whereas line 60 shows measurement resistance values for an unhealthy organ. The more diseased an organ becomes, the higher the resistance of the measurement values. and consequently the greater the difference between the measurement and reference values.

Referring to Figures 13 and 14, the measurement or calibration electrodes are placed on one of the spots indicated in order to obtain a diagnosis of a specific organ. The spot on which the electrode is placed depends on the specified organ, and Tables 1 and 2 set out below show the organs to which the numbered spots refer.

Table 1

Number on Figure 13	Portion of Body
1	Heart (R)
2	Thyroid Gland
3	Lungs (Upper Lobe)
4	Lungs
5	Oesophagus (Cardia)
6	Stomach
7	Liver (Left Lobe) (R)
8	Liver (Right Lobe) (L)
9	Spleen (R)
10	Kidneys
11	Pancreas (R)
12	Gall Bladder (L)
13	Duodenum (L)
14	Transverse Colon
15	Left Colon (R)
16	Right Colon (Appendix) (L)
17	Small Intestine
18	Ureter
19	Bladder
20	Prostate
21	Distal Colon
22	Mammary Gland
23	Ovary & Adnexa Uteri
24	Uterus
25	Pons
26	Thalamus

27	Hypothalamus
28	Hypophysis
29	Cortex (Frontal Lobe)
30	Midcortex
31	Cortex (Posterior)
32	Cerebellum
33	Medulla Oblongata
34	Cervical Spine
35	Thoracic Spine
36	Lumbo-Sacral Spine
37	Shoulder
38	Elbow
39	Wrist
40	Metacarpus
41	Fingers
42	Hip
43	Knee
44	Ankle
45	Metatarsus
46	Toes

(L) - left ear auricle
 (R) - right ear auricle

5

Table 2

Number on Figure 14	Portion of Body
1	Brain
2	Pituitary
3	Thyroid Gland
4	Oesophagus
5	Lungs
6	Heart
7	Liver
8	Cardiac Sphincter
9	Stomach
10	Spleen
11	Gall Bladder
12	Adrenal Glands
13	Pancreas
14	Duodenum
15	Colon
16	Kidneys
17	Small Intestine
18	Ureters
19	Fallopian Tubes
20	Ovaries
21	Bladder
22	Appendix

The invention is not limited to the precise constructional details disclosed in this specification and it will be clear to those skilled in the art that the above principles may be applied produce other apparatus embodying these principles. Specifically, the apparatus as described uses impedance and resistance measurements to calculate the state of health of the organ in question, but it will be clear to those skilled in the art that other values which are either directly or indirectly proportional to resistance or impedance may be used as measurements and in the calculations.

Claims

1. A method for diagnosing a state of health of at least a portion of a human or
5 animal body, the method including the following steps:
applying to the body a potential difference between a reference electrode in
contact with the body and a measurement electrode also in contact with the
body;
controlling either a current value or a voltage value such that the current
10 through the electrodes or the voltage between the electrodes remains within
predefined limits;
monitoring at least a current or a voltage, such that the current or voltage
through or between the electrodes is determinable, until such time as a sudden
and significant change in the monitored current or voltage is observed ;
15 measuring a reference value which is a current, resistance or voltage value
which is dependent on resistance between the electrodes;
altering the potential difference between the electrodes so that the polarity of
the electrodes is inverted;
measuring a measurement value which is a current, resistance or voltage value
20 which is dependent on resistance between the electrodes; and
relating the reference and measurement values to the state of health of the
portion of the body.
2. A method as claimed in claim 1, wherein the controlled voltage or current is a

voltage between the electrodes or a current through the electrodes.

3. A method as claimed in either of claims 1 or 2, wherein the monitored current and/or voltage is the current through the electrodes or the voltage between the electrodes.
- 5
4. A method as claimed in any one of claims 1 to 3, wherein the current is monitored if the voltage is controlled.
- 10 5. An apparatus as claimed in claim 4, wherein the current is monitored until a sudden and significant increase in current is observed.
6. An apparatus as claimed in any one of claims 1 to 3, wherein the voltage is monitored if the current is controlled.
- 15
7. An apparatus as claimed in claim 6, wherein the voltage is monitored until a sudden and significant decrease in voltage is observed.
8. A method as claimed in any one of claims 1 to 7, wherein a resistance between the electrodes is monitored.
- 20
9. A method as claimed in claim 8, wherein the resistance is monitored until a sudden and significant decrease in resistance is observed.

10. A method as claimed in any one of claims 1 to 9, wherein the reference value is measured when the monitored current, voltage or resistance is substantially constant.
- 5 11. A method as claimed in any one of the preceding claims, wherein prior to measurement of the reference value the voltage over the electrodes is adjusted until the current through the electrodes measures a preselected value.
12. A method as claimed in claim 11, wherein the voltage is adjusted until the
10 current reading is between 10 and 50 μA .
13. A method as claimed in claim 12, wherein the voltage is adjusted until the current reading is between 20 and 30 μA .
- 15 14. A method as claimed in any one of claims 1 to 10, wherein prior to measurement of the reference value the current is adjusted until the voltage measures a preselected value.
15. A method as claimed in claim 14, wherein the current is adjusted so that the
20 voltage does not exceed 30 V.
16. A method as claimed in any one of claims 1 to 15, wherein the reference value is the current through the electrodes, the skin resistance between the electrodes, or the voltage between the electrodes.

17. A method as claimed in any one of claims 1 to 16, wherein the measurement value is the current through the electrodes, the resistance between the electrodes, or the voltage between the electrodes.
- 5
18. A method as claimed in any one of the preceding claims, wherein the measurement electrode is placed in contact with a zone of skin on the body corresponding to the portion of the body to be diagnosed.
- 10 19. A method as claimed in any one of the preceding claims, wherein the measurement electrode is a point electrode.
20. A method as claimed in any one of the preceding claims, wherein the measurement electrode is negatively polarised with respect to the reference electrode when the potential difference is first applied to the body prior to the reference value being measured.
- 15
21. A method as claimed in any one of the preceding claims, wherein the portion of the body is an internal organ of the body which corresponds to the part of the body to which the potential difference is applied.
- 20
22. A method as claimed in any one of the preceding claims, wherein the potential difference is applied to the skin of the body.

23. A method as claimed in claim 22, wherein the potential difference is applied to the area of the skin corresponding to the internal organ being diagnosed.
24. A method as claimed in any one of the preceding claims, wherein the state of health of the portion of the body is expressed as a ratio of the reference and measurement values.
25. An apparatus for diagnosing a state of health of at least a portion of a human or animal body, the apparatus including:
- an electrical signal generating means to which at least measurement and reference electrodes are connectable;
- a means for measuring at least one reference parameter from a group including voltage, current and resistance;
- a controlling means which in use, when a potential difference is applied between the electrodes, monitors the reference parameter until there is a significant and sudden change in the reference parameter, whereafter a recording means records a measured value of the reference parameter, whereafter the controlling means changes the voltage between the electrodes such that the polarity of the electrodes is inverted, whereafter a measured value of a measurement parameter is measured and recorded, the measurement parameter being selected from the group including voltage, current and resistance;
- means for comparing the reference and measurement values; and
- means for communicating the comparison to an operator of the apparatus.

26. An apparatus as claimed in claim 25, which includes reference and measurement electrodes.
- 5 27. An apparatus as claimed in either of claims 25 or 26, wherein the reference parameter is the voltage between the electrodes.
28. An apparatus as claimed in claim 27, wherein the voltage is monitored until a sudden and significant decrease in voltage is observed.
- 10 29. An apparatus as claimed in claim 25 or 26, wherein the reference parameter is the current through the electrodes.
30. An apparatus as claimed in claim 29, wherein the current is monitored until a sudden and significant increase in current is observed.
- 15 31. An apparatus as claimed in claim 25 or 26, wherein the reference parameter is the resistance between the electrodes.
- 20 32. An apparatus as claimed in claim 31, wherein the resistance is monitored until a sudden and significant decrease in resistance is observed, whereafter a resistance value is recorded.
33. An apparatus as claimed in any one of claims 25 to 32, wherein the current

through the electrodes or voltage across the electrodes is adjusted until there is a sudden and significant change in the reference parameter.

34. An apparatus as claimed in any one of claims 25 to 33, wherein the value of the reference parameter is only measured once the reference parameter is substantially constant.
35. An apparatus as claimed in either of claims 27 or 28, wherein the measurement parameter is the voltage between the electrodes.
36. An apparatus as claimed in either of claims 29 or 30, wherein the measurement parameter is the current through the electrodes.
37. An apparatus as claimed in either of claims 31 or 32, wherein the measurement parameter is the resistance across the electrodes.
38. An apparatus as claimed in any one of claims 25 to 37, wherein a switching means is provided to invert the polarity of the electrodes.
39. An apparatus as claimed in any one of claims 25 to 28 wherein prior to measurement of the reference value the current through the electrodes is adjusted until the voltage over the electrodes measures a preselected value.
40. An apparatus as claimed in claim 39, wherein the current is adjusted so that the

voltage does not exceed 30 V.

41. An apparatus as claimed in any one of claims 25, 26, 29 and 30, wherein prior to measurement of the reference value the voltage over the electrodes is adjusted until the current through the electrodes measures a preselected value.
42. An apparatus as claimed in claim 41, wherein the voltage is adjusted until the current reading is between 10 and 50 μA .
43. An apparatus as claimed in claim 41, wherein the voltage is adjusted until the current reading is between 20 and 30 μA .
44. An apparatus as claimed in any one of claims 26 to 43, wherein the measurement electrode is a point electrode.
45. An apparatus as claimed in any one of claims 26 to 43, wherein the measurement electrode has a clip portion for attaching the electrode to an auricle of an ear.
46. An apparatus as claimed in any one of claims 25 to 45, wherein the measurement electrode is negatively polarised with respect to the reference electrode when the first potential difference is applied across the electrodes prior to the reference parameter being measured.

47. An apparatus as claimed in any one of claims 25 to 46, wherein the state of health of the diagnosed portion of the body is expressed as a ratio of the reference and measurement values.
- 5 48. An apparatus as claimed in any one of claims 25 to 47, wherein the comparison of the reference and measurement values is communicated to the operator visually or audibly.
49. An apparatus as claimed in any one of claims 47 or 48, wherein the state of health of the diagnosed portion is communicated as being either healthy,
10 normal, sub-acute or acute, depending on the ratio of the measurement and reference values.
50. An apparatus as claimed in any one of claims 25 to 49, which is connectable to
15 a computer or television.
51. An apparatus as claimed in any one of claims 25 to 50, wherein the portion of the body to be diagnosed can be selected.
- 20 52. An apparatus as claimed in claim 51, which includes means for detecting whether or not the measurement electrode has been placed on the zone of skin corresponding to the selected portion of the body.
53. A method of diagnosing a state of health of at least a portion of a human or

animal body, the method including the following steps:

applying an AC signal to the body which passes from a first electrode in contact

with the body to a second electrode also in contact with the body, one of the electrodes being a calibration electrode in contact with a zone of skin in the vicinity of a zone of skin on the body corresponding to the portion of the body to be diagnosed;

measuring a first reference reading which is dependent on the magnitude of the impedance between the electrodes;

substituting a measurement electrode for the calibration electrode, the measurement electrode being in contact with the zone of the skin which corresponds to the portion of the body to be diagnosed;

measuring a comparative reading which is also dependant on the magnitude of the impedance between the electrodes; and

relating the reference and comparative readings to the state of health of the portion of the body.

54. A method as claimed in claim 53, wherein the reference reading is the impedance across the electrodes.

55. A method as claimed in claim 53 or 54, wherein the comparative reading is the impedance across the electrodes.

56. A method as claimed in any one of claims 53 to 55, wherein the measurement electrode has a different skin contact surface area than the calibration electrode.

57. A method as claimed in claim 56, wherein the calibration electrode has a larger skin contact surface area than the measurement electrode.
- 5 58. A method as claimed in any one of claims 53 to 57, wherein the portion of the body is an internal organ of the body which corresponds to the part of the body to which the AC signal is applied.
59. A method as claimed in any one of claims 53 to 58, wherein the AC signal is
10 applied to the skin of the body.
60. A method as claimed in claim 58 or 59, wherein the AC signal is applied to the area of the skin corresponding to the internal organ being diagnosed
- 15 61. A method as claimed in any one of claims 53 to 60, wherein the frequency of the AC signal is 250 Hz.
62. A method as claimed in any one of claims 53 to 61, wherein the state of health of the portion of the body is expressed as a ratio of the comparative and
20 reference readings.
63. An apparatus for diagnosing a state of health of at least a portion of a human or animal body, the apparatus including:
an AC signal generator to which at least two electrodes are connectable;

a measuring means which in use measures a parameter which depends on the magnitude of the impedance between the electrodes;
a recording means for recording at least two values of the parameter;
a comparison means for comparing the two values; and
5 a communicating means for communicating the comparison of the values to an operator of the apparatus.

64. An apparatus as claimed in claim 63, which includes reference, calibration and measurement electrodes.

10

65. An apparatus as claimed in claim 64, wherein the calibration electrode has a larger skin contact surface area than the measurement electrode.

15

66. An apparatus as claimed in any one of claims 63 to 65, wherein the frequency of the AC signal is 250 Hz.

67. An apparatus as claimed in any one of claims 63 to 66, wherein the state of health of the portion of the body is expressed as a ratio of the two values.

20

68. An apparatus as claimed in any one of claims 63 to 67, wherein the portion of the body to be diagnosed can be selected.

69. An apparatus as claimed in claim 68, which includes means for detecting whether or not the measurement and calibration electrodes have been placed on

the zone of skin corresponding to the selected portion of the body.

70. An apparatus for diagnosing a state of health of at least a portion of a human or animal body, the apparatus including:
- 5 an apparatus as claimed in any one of claims 25 to 52; and
- an apparatus as claimed in any one of claims 63 to 69.
71. A method or apparatus, substantially as herein described and illustrated.
- 10 72. A new method or a new apparatus substantially as herein described.

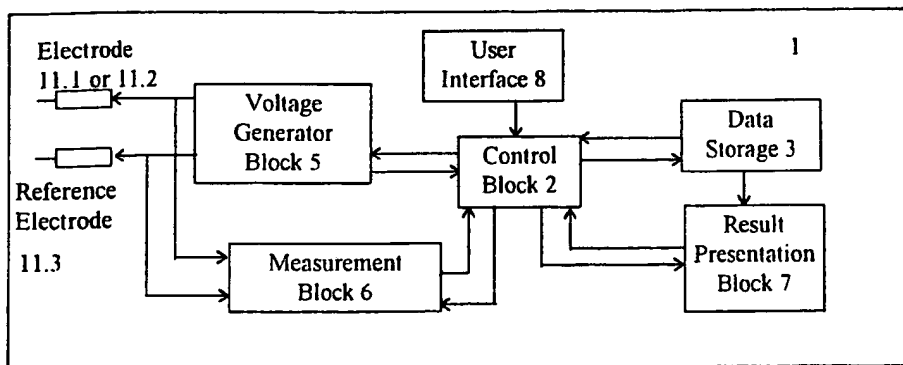


Figure 1

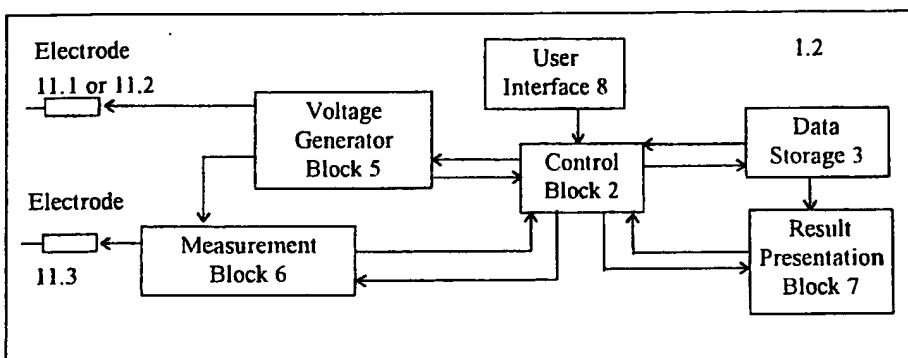
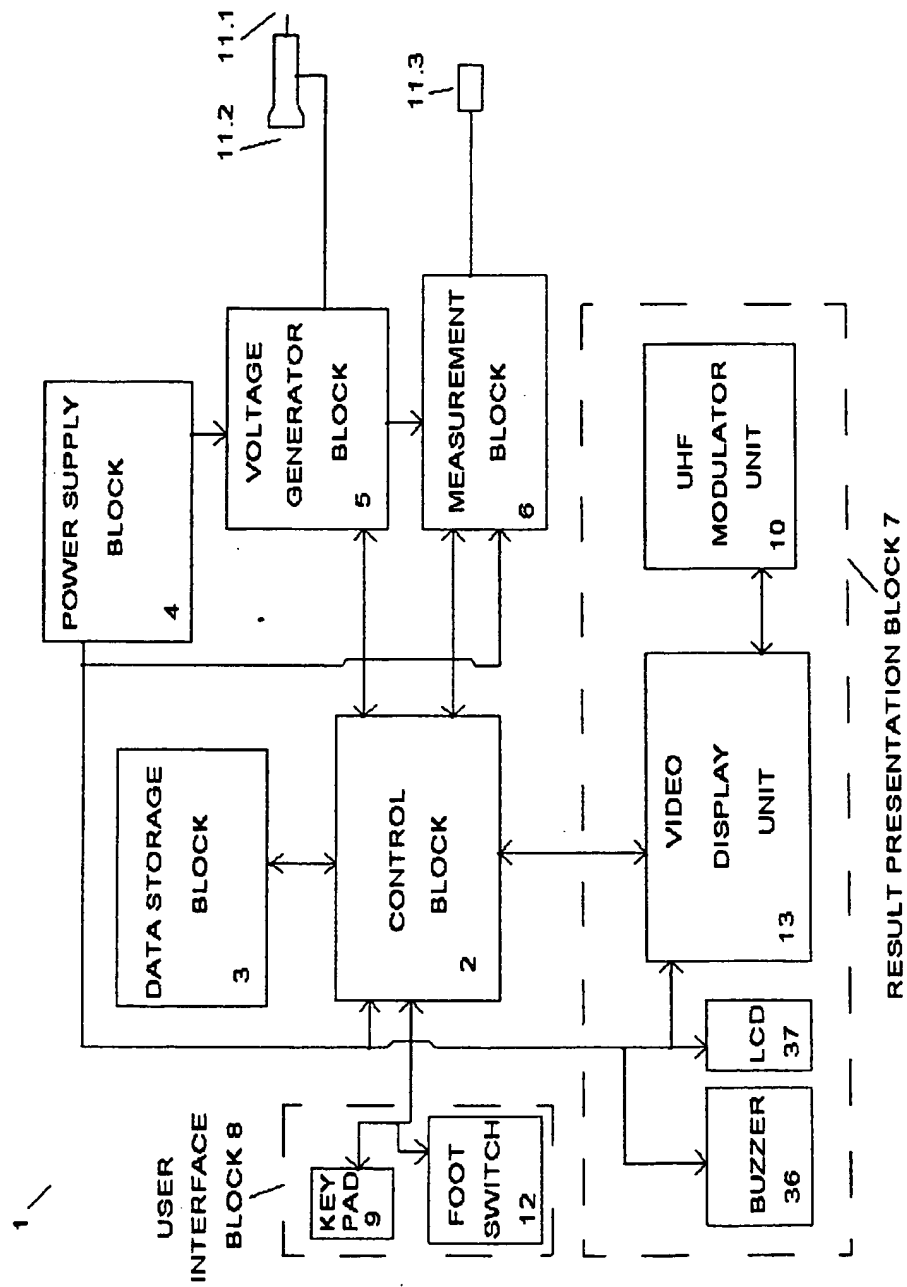


Figure 2

FIGURE 3



POWER SUPPLY BLOCK 4

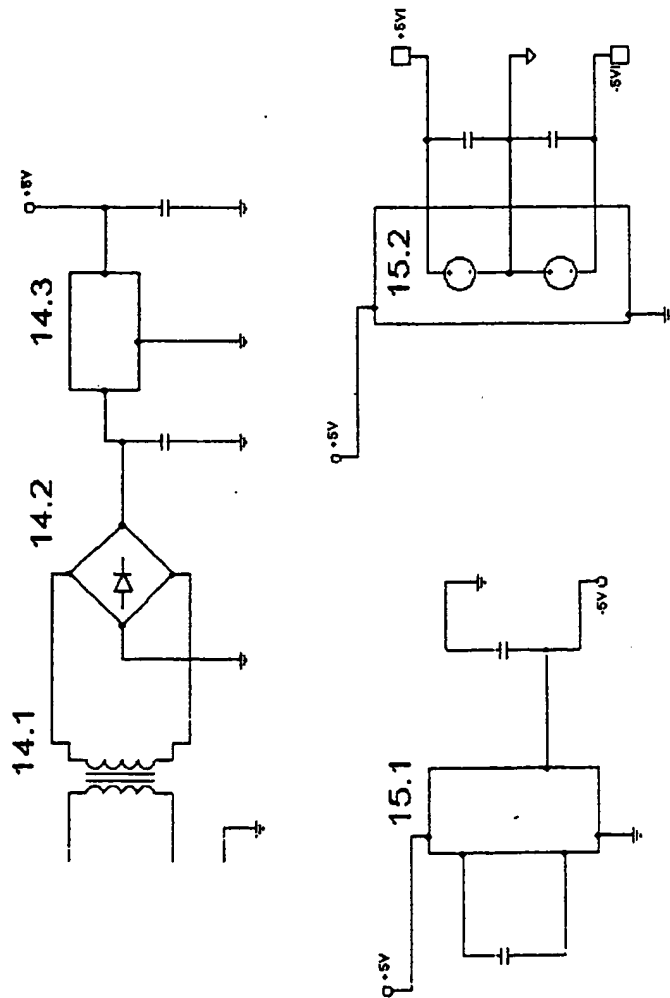
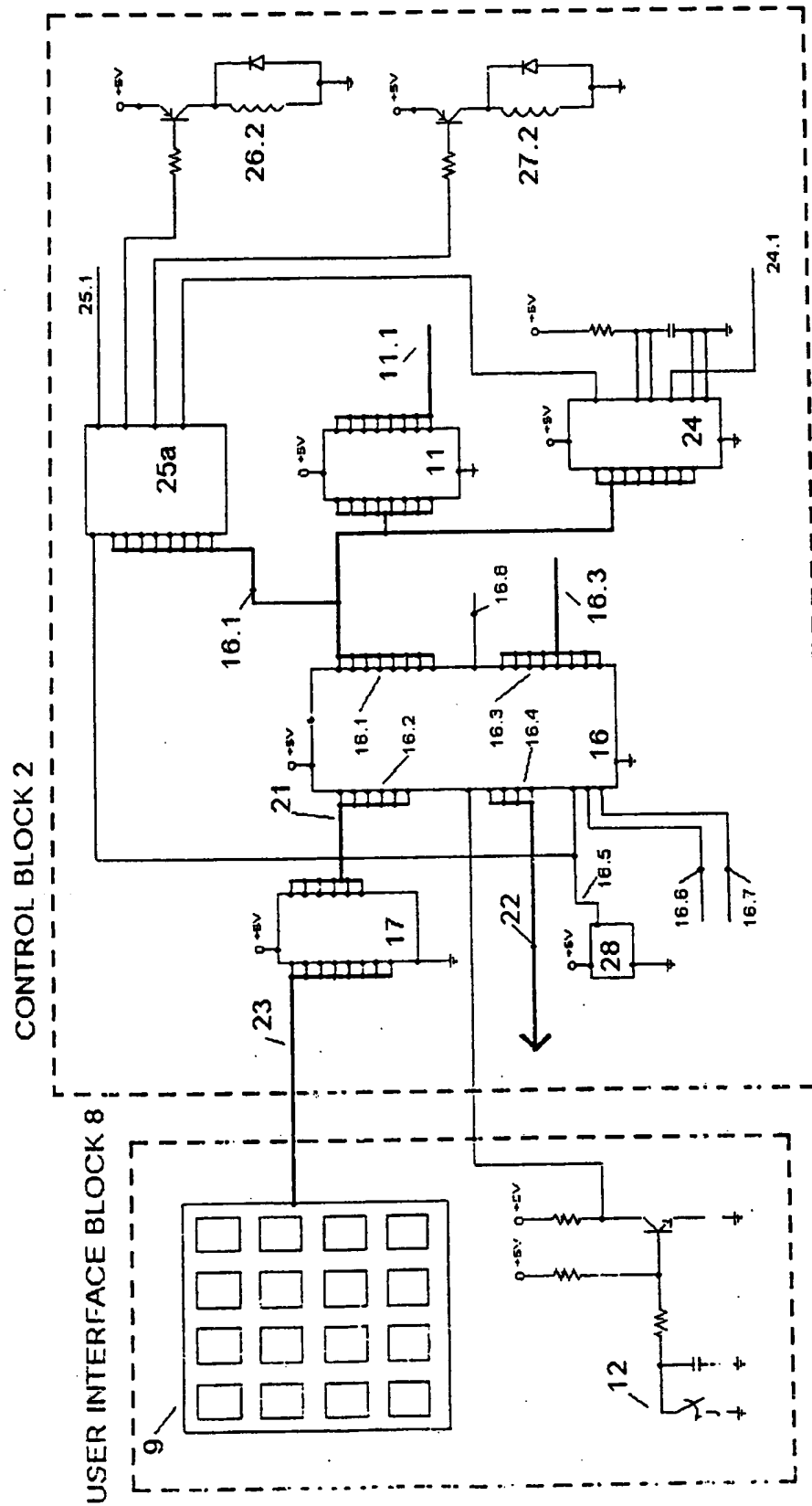


FIGURE 4

FIGURE 5



RESULT PRESENTATION BLOCK 7

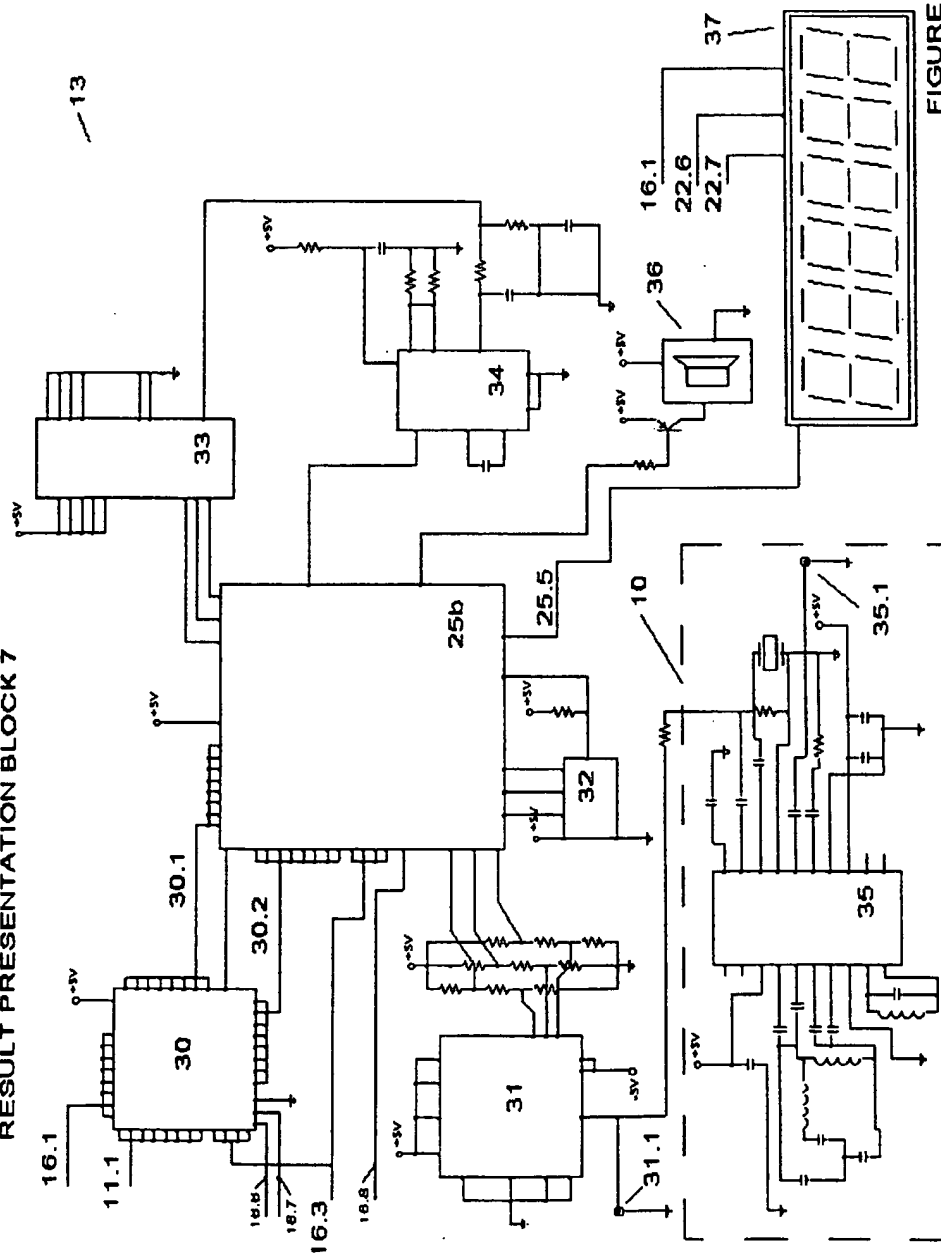
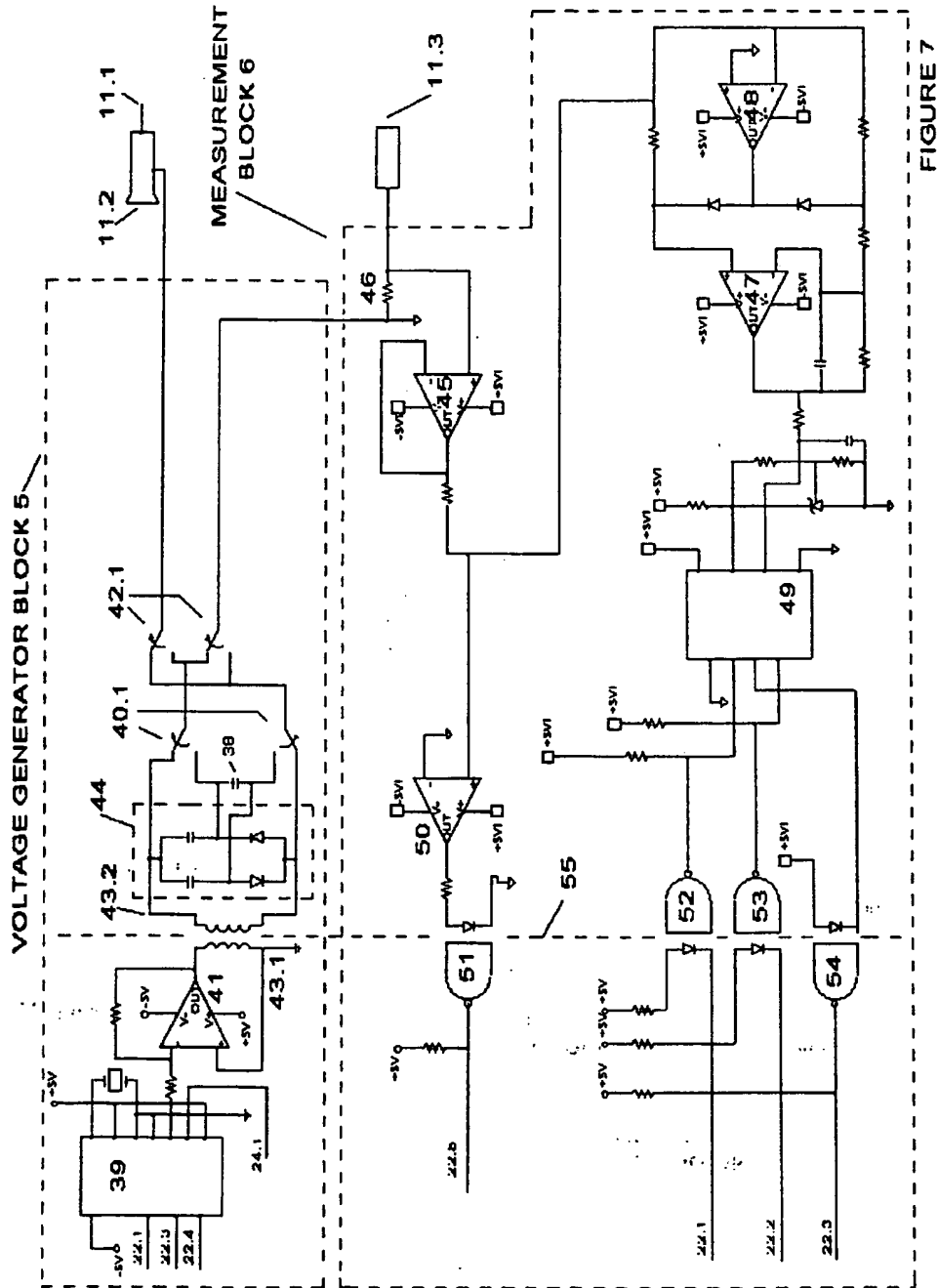
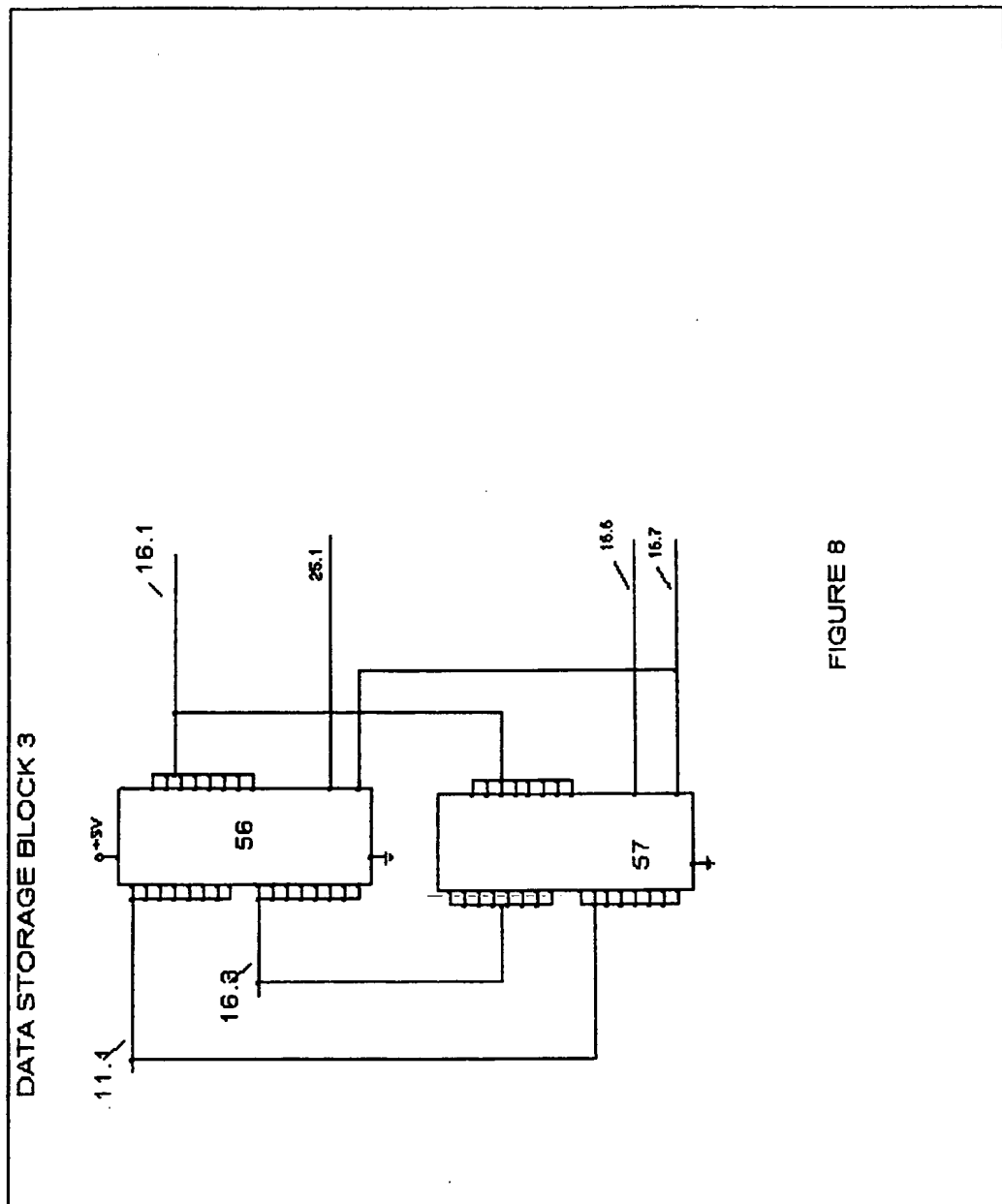
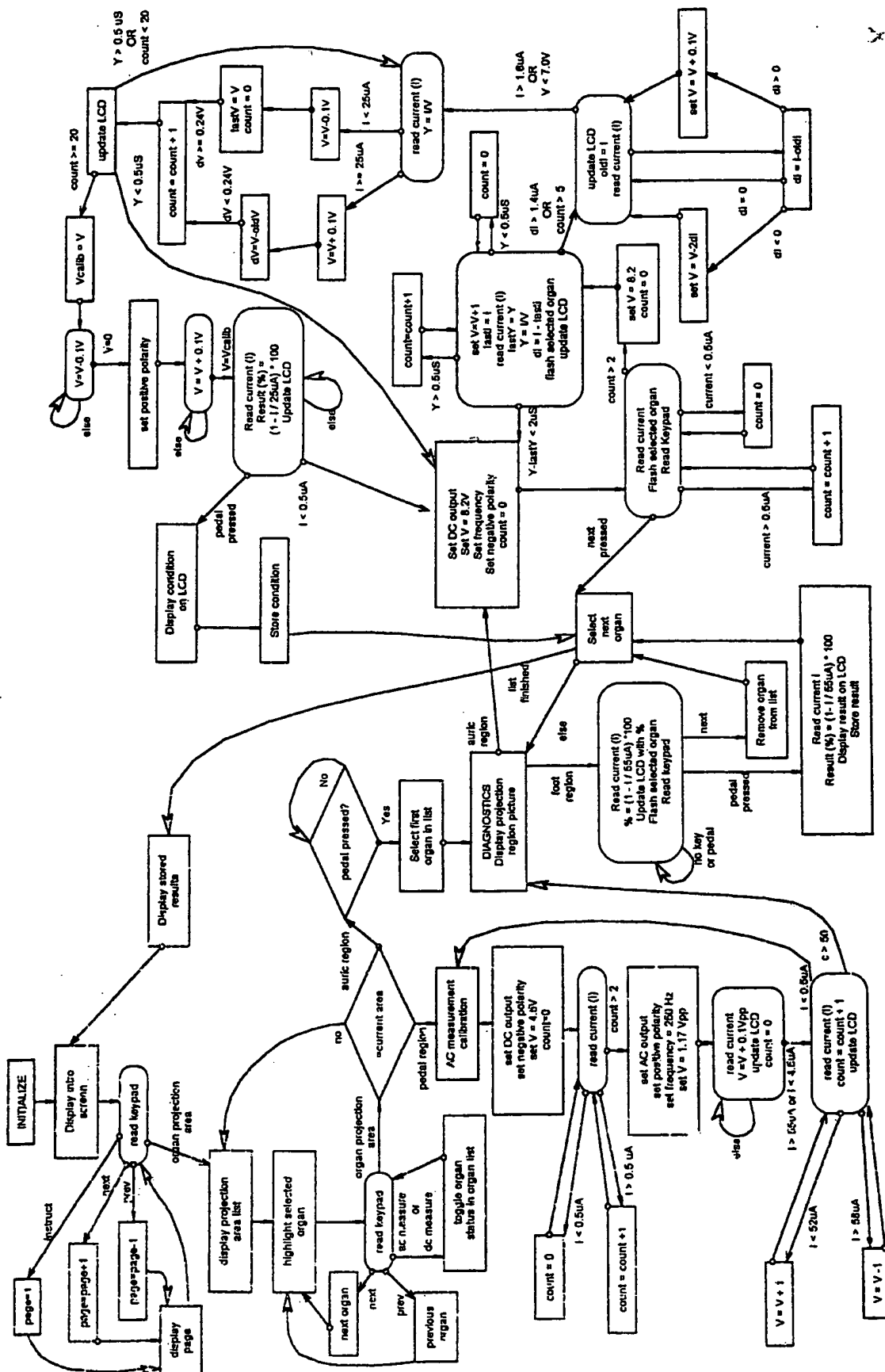


FIGURE 6







9/13

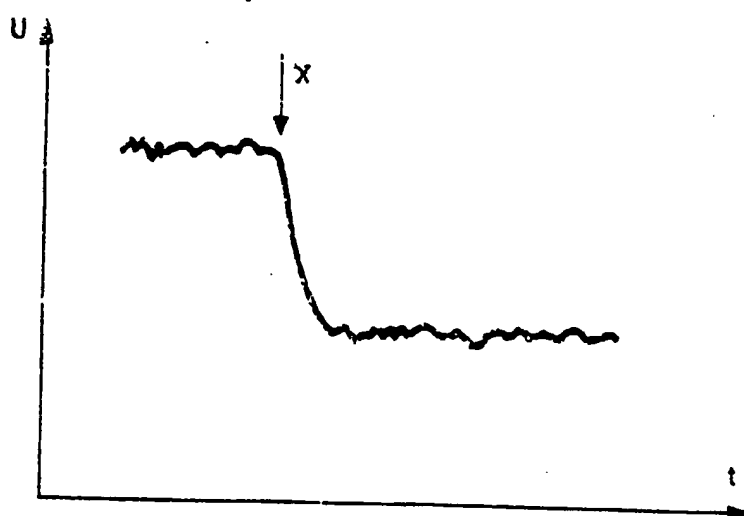


Figure 10

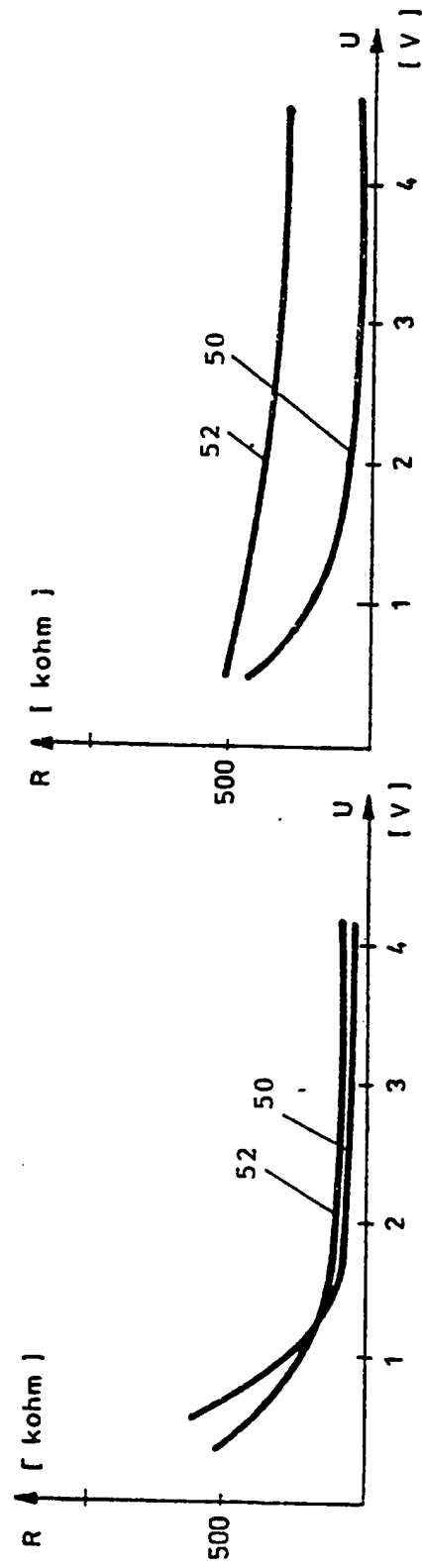


Figure 11a

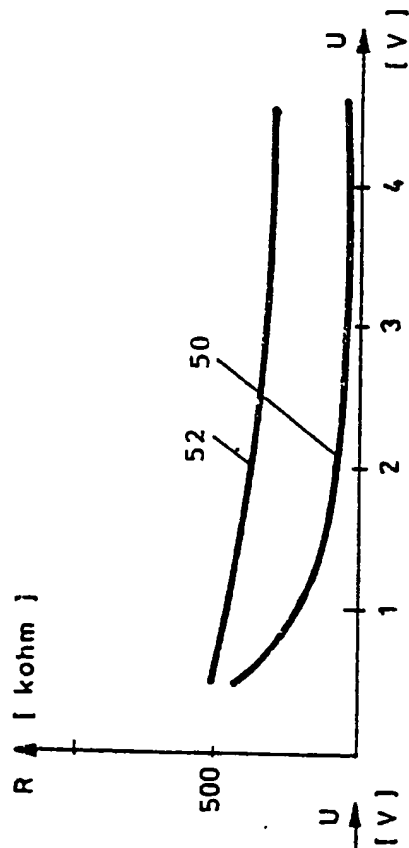


Figure 11b

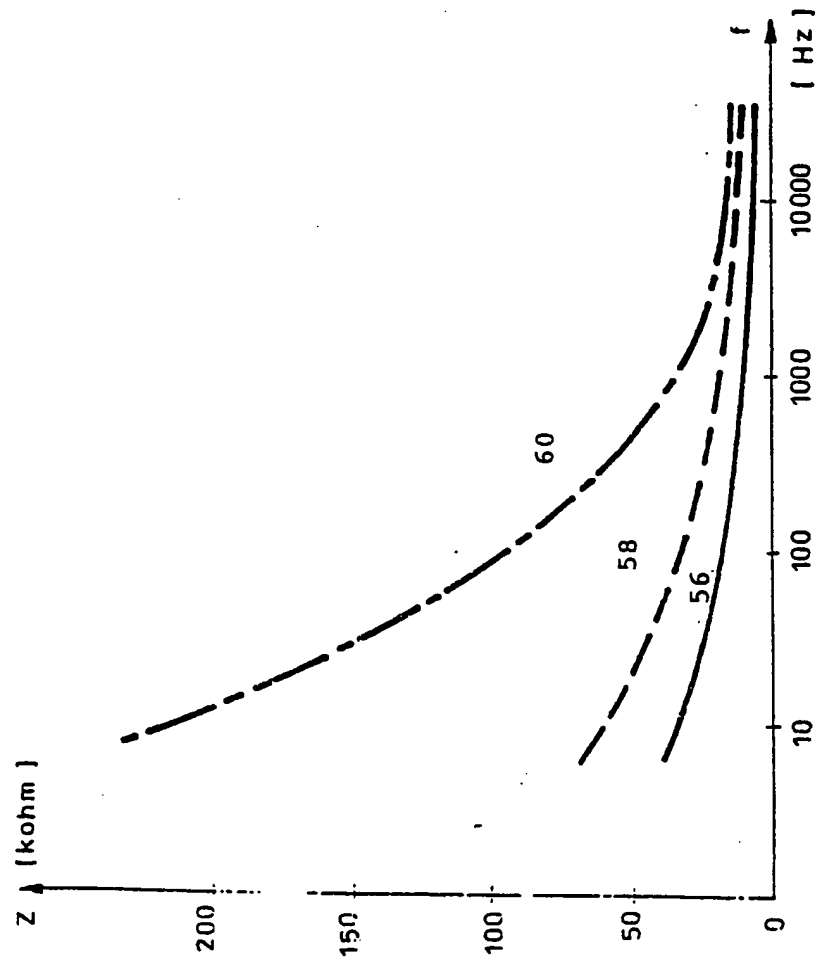


Figure 12

12/13

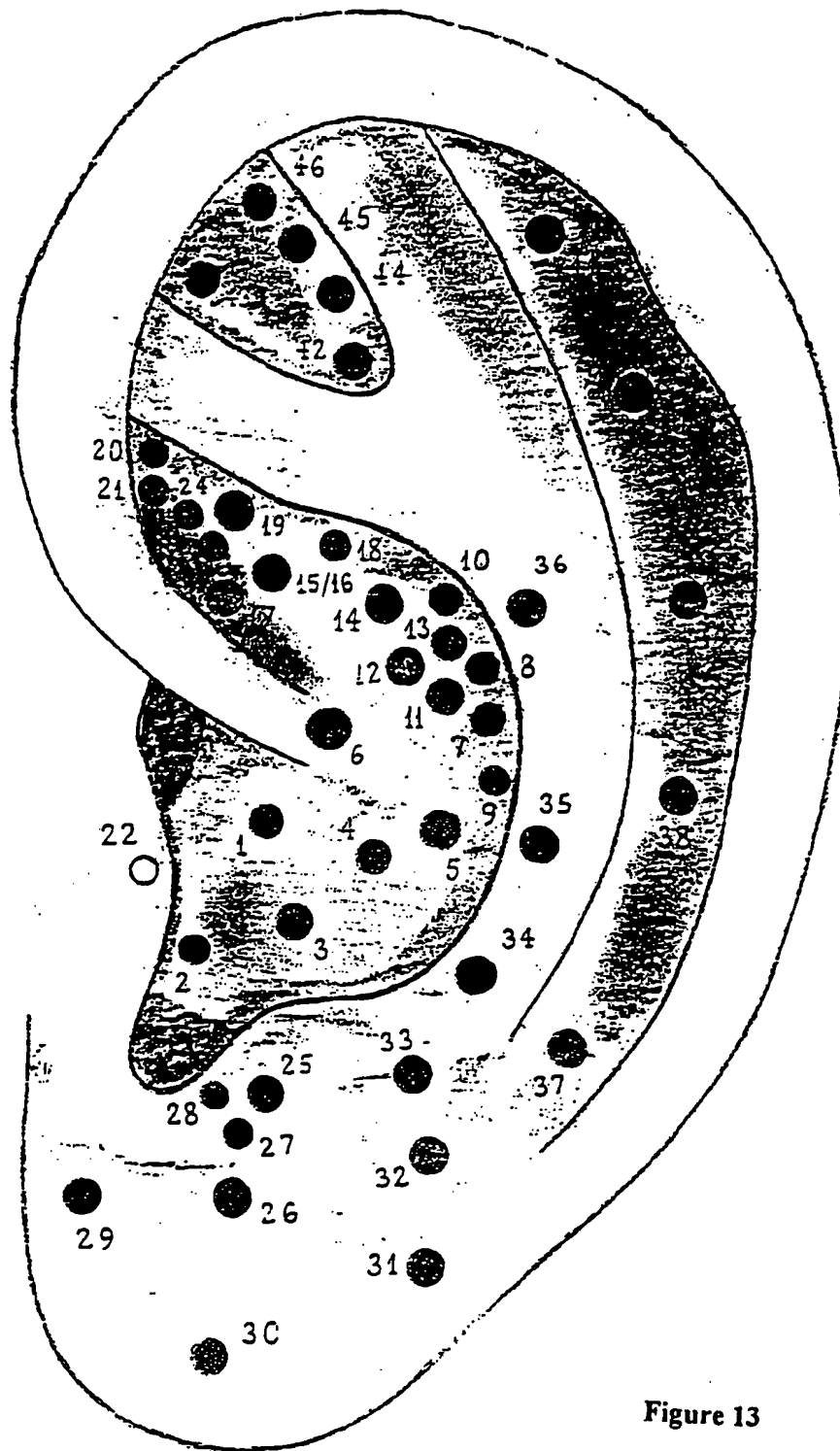


Figure 13

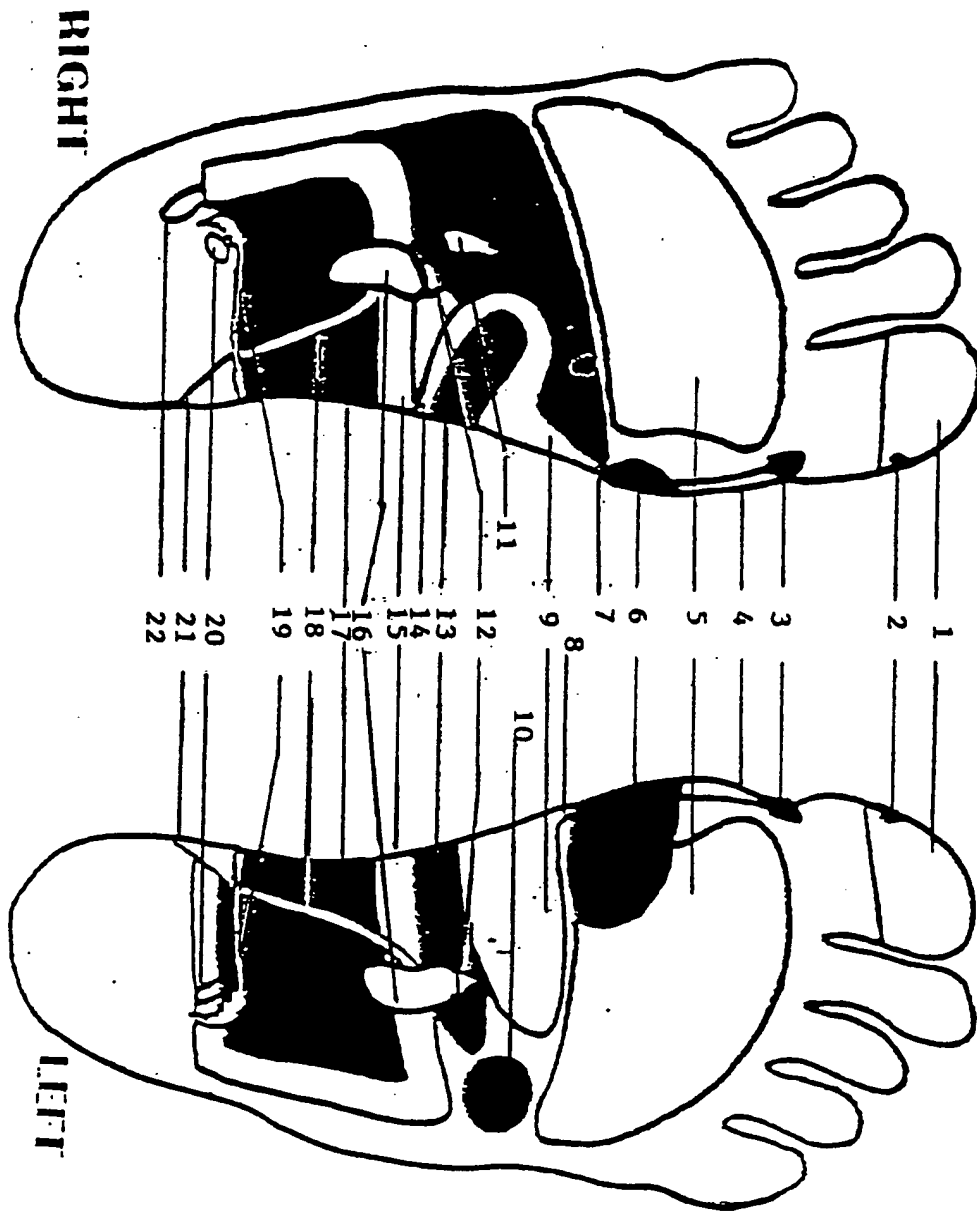


Figure 14

INTERNATIONAL SEARCH REPORT

International Application No

PCT/ZA 99/00048

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/05

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	WO 91 11957 A (MCRAE DONALD A) 22 August 1991 (1991-08-22) page 5, line 3 -page 7, line 4 ---	63,66, 68,71,72 1,25,53, 70
A	US 3 971 366 A (MOTOYAMA HIROSHI) 27 July 1976 (1976-07-27) column 3, line 28 - line 65 column 5, line 9 - line 68 column 7, line 15 -column 10, line 34 ---	1,25,53, 63,70
A	US 4 160 447 A (TESHIMA TORU ET AL) 10 July 1979 (1979-07-10) column 3, line 52 -column 4, line 62; claim 1 --- -/--	1,25,53, 63,70

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

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- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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Date of the actual completion of the international search

5 November 1999

Date of mailing of the international search report

16/11/1999

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Martelli, L

INTERNATIONAL SEARCH REPORT

International Application No

PCT/ZA 99/00048

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 016 870 A (LOCK CHUCK) 12 April 1977 (1977-04-12) column 2, line 55 -column 3, line 41 ---	1,25,53, 63,70
A	WO 98 26714 A (WEIJAND KOEN) 25 June 1998 (1998-06-25) page 4, line 11 -page 5, line 25 -----	1,25,53, 63,70

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/ZA 99/00048

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US 3971366	A	27-07-1976	NONE	
US 4160447	A	10-07-1979	NONE	
US 4016870	A	12-04-1977	NONE	
WO 9826714	A	25-06-1998	US 5772605 A	30-06-1998
			AU 5530298 A	15-07-1998